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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,016

06/15/2006

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RCHP-102US

6107

23122 7590 12/09/2009  
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EXAMINER

TOSCANO, ALICIA

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

12/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,016	<b>Applicant(s)</b> SHASTRI ET AL.	
	<b>Examiner</b> Alicia M. Toscano	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-12, 14-18, 22-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-12, 14-18 and 22-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. Rejection over Claims 23, 24 and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is overcome by amendment.
2. Rejection over Claims 8 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is overcome by amendment.

***Claim Objections***

3. Objection over Claim 5 is overcome by amendment.
4. Objection over Claims 10-12 is overcome by amendment.
5. Objection over Claim 28 is overcome by amendment.
6. Objection over Claim 36 is overcome by amendment.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 5-12, 14-18, 22-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Spinu (US 5202413).

This rejection is as set forth in the action dated 4/28/09, reiterated below in its entirety. The claims have been amended to reflect the newly canceled claims and to reflect the lactone unit requirements of the claims. See remarks below.

Spinu discloses alternating ABAI polylactide block copolymers (title). The "A" block comprises lactide units derived from ring opening lactones such as those disclosed in Column 4. The "B" block is a diol having a number average MW of 500-20,000 and may be a dihydroxy ether such as polyethylene oxide and the like (Column 3 lines 25-69 and examples). This unit may be derived from ethylene glycol, the derivation requirements is a product by process limitation, hence the methods they are created by are not pertinent, unless applicant can show a different product is produced. The "I" coupling unit, which links ABA block copolymers together, may be diacyl chlorides having 8-20 carbon atoms, which encompasses sebacic acid, dodecanoic acid and the like, is disclosed in Column 5 line 15. Catalysts such as stannous 2-ethylhexanoate are used to react the diol with the lactone (Column 4 lines 61-62). Since the MW of the blocks is at least 500, preferably at least 2000 which given a lactide MW of 144 means at least 4 to 14 lactide units are present, the m requirements of the claims are met. Since the composition requirements of the claims are met the properties of claim 18 are found to be inherently met by the composition. The number of units linked by the coupling agent can be from 1 to 100 (Column 3 line 16), as further required by claim 5. The above elements meet the requirements of claims 5, 6, 7, 14-16, 26-32. Since the lactone units always inherently comprise at least 80% of the polyester (i.e 2 A units and

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at least 4 repeats therein equals 8 A units, plus 1 B unit and 1 C unit,  $8/10=80\%$ ) claims 8 and 9 are met. The lactide MW blocks of at least 500 meet the requirements of claims 10-12. The end product has a number average MW of 10,000-250,000 (Column 5 line 27), since the weight average MW is higher than the number average MW the range of claim 17 is met therein. Since the end MW and the lactone unit requirements of the claim are met it is the Examiner's position that the molar ratio is inherently met by Spinu, additionally, Ex 2 discloses a molar ratio of 71:1, Ex 3 discloses a molar ratio of 23:1, Ex 9 discloses a molar ratio of 14:1, as such the limitations of claims 23 and 24 are deemed met. The coupling agent added in a 1:1 ratio Column 5 line 17, as required by claim 25. Since there is no structural limitation of a device required in the claims the Examiner finds the end molded resins to meet the requirements of claim 33. Since there is no disclosure as to how one adapts the device in claims 34 and 35 the Examiner finds the mere molding of an article to meet the adaptation requirement and finds the limitations of the claims met.

Remarks:

Applicant argues Spinu's blocks are derived from polyethers and the like having a MW from 500 to 20000, which does not meet the amended claims.

The Examiner disagrees. The claims language "diol residues derived from" is met by Spinu since the 500 to 20000 MW diol of polyethylene oxide (See Ex 6) may be derived from ethylene glycol, which meets the claim limitations. As such Applicant's arguments are not persuasive and the rejection stands as set forth above.

8. Rejection over Claims 1-14, 18-20, 22-25, 27-30 and 33-35 under 35 U.S.C. 102(b) as being anticipated by Fowler (US 2977385) are overcome by amendment, the lactones of Fowler are outside the lactone requirements of claim 5 and Fowler teaches away from using lactones with fewer carbon atoms (Column 1 lines 45-44).

9. Claims 5-12, 14-18, 22, 25-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohn (US 5711958).

This rejection is as set forth in the action dated 4/28/09, reiterated below in its entirety. The claims have been amended to reflect the newly canceled claims and to reflect the lactone unit requirements of the claims. See remarks below.

Cohn discloses polymeric compositions comprising chain extended hydroxy-carboxylic acid/polyoxyalkylene ABA triblocks (abstract). The A block is derived from lactide, glycolic and various lactones (Column 3 lines 31-35), the B block may be polyethylene oxide and the like. This unit may be derived from ethylene glycol, the derivation requirements is a product by process limitation, hence the methods they are created by are not pertinent, unless applicant can show a different product is produced. The chain extender may be diacyl halides formed from derivatizing dicarboxylic acids (Column 6 lines 43-44), wherein the dicarboxylic acids may be sebacic and the like (Column 14 lines 35-50). The molar ratio of the chain extender to the ABA copolymer is

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1:2 to 2:1 (Column 9 lines 48-50). The catalyst used to react the diol and lactone may be stannous octoate, which is a synonym for tin-2-ethylhexanoate (see the attached chemical data sheet). The A block may have 4-50 units therein (Column 4 line 45), as required by claims 5 and 6 and since the molar ratio and difunctionality of the coupling agent is met, the x macromeric units are found to be encompassed by the teachings of Cohn, as further required by claim 5. Elements above meet the requirements of claims 5, 6, 7, 14-16, 22, 25-32. Since the composition requirements are met the properties of claim 18 are deemed inherently met by the composition. Since the lactone units always inherently comprise at least 80% of the polyester (i.e 2 A units and at least 4 repeats therein equals 8 A units, plus 1 B unit and 1 C unit,  $8/10=80\%$ ) claims 8 and 9 are met. A lactone unit would have a MW of 144. Cohn discloses 4-50 units of lactic acid, or approx 2-25 units of lactone, resulting in a MW rang of 288-3600, which meets the requirements of claims 10-12. The MW of the triblock spans 1,000-30,000, and as such when one chain extends with a 1:1 molar ratio one would expect a doubling of the MW, encompassing the range of claim 17. The resulting compositions are used to deliver bioactive compositions such as antibodies and the like (Column 16 lines 28-56). There is no structural limitation of device or process limitation of the adaptation and as such the delivery vehicle described by Cohn is found to meet the limitations of claims 33-36.

## Remarks:

Applicant argues Cohn does not teach a B block containing the C2-C14 groups presently claimed.

The Examiner disagrees. The claims language "diol residues derived from" is met by Cohn since the B block diol of polyethylene oxide (Column 3 line 45) may be derived from ethylene glycol, which meets the claim limitations. As such Applicant's arguments are not persuasive and the rejection stands as set forth above.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claim 36 is rejected under 35 U.S.C. 103(a) as being obvious over Spinu (US 202413) in view of Cohn (US 5711958).

Elements of this rejection are as set forth in the action dated 4/28/09, reiterated below in its entirety, see remarks below.

Spinu includes elements as set forth above. Spinu discloses ABAI type degradable molded resins. Spinu does not disclose the use of bioactive agents with said resin.

Cohn discloses methods for reducing post surgical adhesion formation. Cohn discloses using ABA triblocks comprising lactic acid-A blocks and diol-based B blocks (Column 3 lines 28-46), the same structure and monomer elements used by Spinu. Cohn also discloses linking the blocks together with acyl acids to form ABAI type degradable resins (Column 3 line 50). Cohn and Spinu thusly disclose very similar polymer compositions. Cohn discloses that such compositions are suitable for use in



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vivo to prevent surgical adhesion, and further discloses the incorporation of bioactive agents such as antibodies and the like (Column 16 lines 28-56) to further promote wound healing.

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In light of such it would have been obvious to one of ordinary skill in the art at the time of the invention to use the composition of Spinu in surgical healing, as taught by Cohn, since it is known in the art to be useful for such. Additionally, it would have been obvious to one of ordinary skill to include in Spinu the use of the bioactive agents taught by Cohn to enhance the healing of the surgical wounds to which the composition was applied to.

Remarks:

Applicant argues Cohn does not make up for the deficiencies of Spinu, the Examiner disagrees, Spinu is not deficient for the reasons set forth above, as such the combination is found proper and stands.

11. Rejection over Claims 15, 16, 17, 21, 31 and 32 under 35 U.S.C. 103(a) as being unpatentable over Fowler in view of Spinu is overcome for the reasons set forth in Fowler above.

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12. Rejection over Claim 26 under 35 U.S.C. 103(a) as being unpatentable over Fowler and McLain (US 5028667) is overcome for the reasons set forth in Fowler above.

13. Rejection over Claim 36 under 35 U.S.C. 103(a) as being obvious over Fowler (US 2977385) in view of Cohn (US 5711958) is overcome for the reasons set forth in Fowler above.

14. Rejection of Claim 19 under 35 U.S.C. 103(a) as being unpatentable over Cohn in view of Fowler is overcome by amendment, said claim is now cancelled.

15. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn in view of Fowler.

Elements of this rejection are as set forth in the action dated 4/28/09, reiterated below in its entirety, see remarks below.

Cohn includes elements as set forth above. Cohn discloses various EO/LA ratios however Cohn does not disclose the molar ratio of the reactants.

Fowler includes elements as set forth above. As set forth, Cohn and Fowler disclose similar chain extended lactone ABA polymers. Fowler discloses that one can control the average molecular weight of the product by preselecting the molar proportions, or ratio, of lactone to initiator (diol). For example, if one desires a MW 10

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times larger than the initial MW the proportions of lactone to initiator are 10:1 (Column 10 lines 60-75). Fowler teaches that higher MW polymers have greater elasticity (Column 11 line 20). Fowler thusly teaches the choice of molar ratio to be a result effective variable.

It would have been obvious to one of ordinary skill in the art at the time of the invention to manipulate the ratios taught in Cohn, as taught by Fowler, in order to obtain the desired end molecular weight to obtain the desired elasticity and tensile strength properties.

Remarks:

Applicant argues Fowler does not make up for the deficiencies of Cohn, the Examiner disagrees, Cohn is not deficient for the reasons set forth above, as such the combination is found proper and stands.

### ***Conclusion***

16. As set forth previously: The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "X" reference US 5346966 is similar in content to Spinu set forth above (also an "X" reference) and as such an additional rejection in view of '966 was deemed unnecessary at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is (571)272-2451. The examiner can normally be reached on M-F 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT

/Randy Gulakowski/

Supervisory Patent Examiner, Art Unit 1796